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No. 07-186

In The Supreme Court of the United States

CROSS MEDICAL PRODUCTS, INC.,
PETITIONER,

V.

MEDTRONIC SOFAMOR DANEK, INC.
AND MEDTRONIC SOFAMOR DANEK USA, INC.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF OF PETITIONERS

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ARGUMENT

The Federal Circuit's articulation and application of the standard for rebutting prosecution history estoppel is deeply flawed and inconsistent with this Court's precedents. Respondents correctly note that petitioner amended claim 5 of the '555 Patent to add a thread depth limitation—and protest that their own product uses threads that are not as long as the claim recites. Standing alone, however, that proves only that respondents' product does not literally infringe that claim. It does not speak to whether there is infringement under the doctrine of equivalents. Like the Federal Circuit, respondents attempt to obfuscate the *reason* that petitioner added a thread depth limitation, which was merely to explain more fully one way that the invention could be "enabled" (i.e., made to work). Petitioners could have specified any number of other ways the nut could have been tightened against the rod, including the inconsequential variation that respondents have used.

Under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), the *rationale* underlying this amendment thus bears no more than a tangential relationship to the "equivalent" respondents have employed. The Federal Circuit acknowledged that the reason for this amendment was merely to enable the invention, but then wholly ignored that reason and focused instead on the *result* of the amendment (i.e., its subject matter) when holding that prosecution history estoppel applies here. The Federal Circuit's recent decisions have consistently ignored that crucial distinction, with the consequence that prosecution history estoppel has essentially swallowed the doctrine of equivalents. This fundamental misstatement of the law must be corrected.

1. Respondents' opposition brief labors to make the Federal Circuit's statement of the law and subsequent analysis consistent with *Festo* by trying to create the impression that the *reason* for the disputed amendment was to disclaim subject matter related to thread depth. But the

Federal Circuit agreed that the Patent Examiner's objection that led to the disputed amendment was based on the enablement requirement. *See* 35 U.S.C. § 112; Pet. App. 7a. The Examiner did not require the patentee to disclaim subject matter that lacked threads that extend "to a depth below the diameter of the rod," in order for the invention to be patentable. Requiring that the threads extend below the diameter of the rod was just one way the patentee was able to demonstrate that the nut would make direct contact with the rod, thus stabilizing the rod without the use of a cap. In other words, the purpose of the amendment was to overcome the enablement rejection by demonstrating one way in which the device could work. But the patentee had other options to overcome the same enablement rejection—including the trivial variation that respondents employed here in a transparent effort to circumvent claim 5 of the '555 Patent. Under these circumstances there is no reason for prosecution history estoppel to displace the doctrine of equivalents.

Respondents, like the Federal Circuit, contend that "this rationale was not tangential to the accused equivalent because the accused equivalent 'does *not* include threads extending "to a depth below the top of the stabilizer" and correspondingly does *not* capture'" the subject matter disclaimed by the patentee. *See* Brief in Opposition at 15 (quoting Pet. App. 12a). Again, however, that is just a long way of saying that respondents' device is not literally within the claims, as amended. That analysis fails to engage at all with the *reason* for the amendment, and instead applies prosecution history estoppel whenever the *subject matter* of the amendment bears a more than tangential relationship to the accused equivalent. The consequence is that a crafty infringer can always look back to some amendment that was made by the patent owner, and then make a trivial modification to his product that implicates that amendment.

By focusing on the *rationale underlying the amendment*, this Court recognized in *Festo* that the patent prosecution process frequently requires patentees to amend claim

limitations for numerous reasons, and that the particulars of the amendment process, rather than the subject matters touched by that process, define the scope of prosecution history estoppel. As the petition explained, if the patentee amends his patent claims on a box to specify that it be held together with glue, a product held together with rubber cement may still infringe under the doctrine of equivalents. Prosecution history estoppel is appropriate if the *reason* for the amendment was to avoid prior art involving rubber cement, or an objection by the examiner that a box held together with rubber cement is too obvious to be patented. But prosecution history estoppel *is not* appropriate if the amendment was to avoid prior art involving boxes that could be disassembled, or (as here) simply an objection that the invention was not fully enough described to allow a competent person to build it.

The Federal Circuit's reformulation of the test in this and other recent cases completely abandons those critical distinctions, and treats the rationale of the amendment as irrelevant so long as its subject matter encompasses the accused equivalent. This test contravenes *Festo* and upsets the balance this Court carefully crafted between prosecution history estoppel and the doctrine of equivalents. The Federal Circuit's analysis unfairly excludes subject matter that should be protected to give effect to the doctrine of equivalents and to this Court's recognition that a patent extends beyond the claim's literal terms to protect inconsequential variation. In light of the Federal Circuit's new legal standard for the tangential relation test, prosecution history estoppel is now essentially an insurmountable bar. Thus, the Federal Circuit has essentially resurrected the pre-*Festo* "complete bar" against the doctrine of equivalents upon claim amendment. This critical error should be corrected.

2. The Federal Circuit has not merely misapplied a correctly stated legal principle to the facts of this case, as respondents argue.

Petitioner does not dispute the Federal Circuit's application of law to facts, but its profoundly important reframing of the basic legal issue. This Court's tangential relation test asks whether the equivalent in question bears no more than a tangential relationship to the reason for the amendment. The Federal Circuit, however, has reformulated the test to instead ask whether "the accused equivalent ... *relates to the amendment.*" Pet. App. 12a (emphasis added). This flawed statement of the law is a direct result of the Federal Circuit's fundamentally incorrect understanding of the "tangential relation" test for rebutting the presumption of prosecution history estoppel.

Of course respondents are correct that the standard for rebutting a presumption of prosecution history estoppel, when properly understood, is a fact-intensive inquiry in any particular case. But that does not counsel against review by this Court to correct the Federal Circuit's misunderstanding (and mis-articulation) of the governing legal standard. A lower court's primary function is to apply legal standards to complex facts, and this frequently requires fact-intensive inquiries. Review remains appropriate where a lower court misstates the law in a manner that rises to national importance.

The legal question involved here is of national importance because it goes to the core of the delicate balance this Court has achieved between prosecution history estoppel and the doctrine of equivalents. *See Festo Corp.*, 535 U.S. at 732 (noting that while "the doctrine of equivalents renders the scope of patents less certain," this is "the price of ensuring the appropriate incentives for innovation"); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) (confirming continued vitality of doctrine of equivalents); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950) (doctrine of equivalents prevents conversion of patent protection into "a hollow and useless thing"). The importance of this legal issue is amplified because the Federal Circuit, unlike regional circuit

courts, creates binding precedent on every district court in the country. This Court is the only judicial body with the ability to rein in the Federal Circuit when it evidences an intent to abandon this Court's precedents. *See, e.g.*, Pet. App. 17a-22a (Rader, J., concurring).

3. Respondents contend that the Federal Circuit's enunciation of the law in this case is consistent with its statement of the law in prior Federal Circuit cases. To a substantial extent they are correct—which just further highlights that this is not a one-time aberration or misapplication of properly stated rules. This case is one of several recent cases in which the Federal Circuit has decisively broken from the correct approach to prosecution history estoppel (focusing on the reason for an amendment) in favor of a new analysis (focusing on the subject matter of an amendment) that is entirely inconsistent with *Festo*.

Respondents identify *Research Plastics, Inc. v. Federal Packaging Corp.*, 421 F.3d 1290 (Fed. Cir. 2005), as an example of the Federal Circuit's "proper" articulation of the legal standard and subsequent "proper" application of that law to the facts of the case. In *Research Plastics*, the Federal Circuit actually misstated the test in a manner similar to its error here. That error was, however, harmless in *Research Plastics* because on the facts of that case both the result of the amendment and the rationale underlying the amendment supported estoppel, and the Federal Circuit was not called upon to distinguish between these important concepts.

In *Research Plastics*, the patent at issue and accused equivalent related to rib placement on the interior surface of caulking tubes. 421 F.3d at 1292. The Federal Circuit first determined that an amendment was made during prosecution to overcome a prior art rejection related to rib placement. The Court next considered that the accused equivalent contained ribs placed in a location that had been disclaimed by the amendment. It concluded that prosecution history estoppel applied and had not been rebutted, because "the alleged equivalent—ribs extending to a point short of the

rear edge of the tube—is not tangential to the purpose of the amendment, because the purpose of the amendment was to avoid rejection based on rib placement." *Id.* at 1299.

As in this case, the Federal Circuit grossly oversimplified the issue in *Research Plastics*. The articulation quoted above contains a subtle reformulation of the test for rebutting prosecution history estoppel, when contrasted with the test as laid down by this Court in *Festo*. In a superficial sense it will *always* be true that the "purpose" of an amendment is "to avoid rejection based on" the prior absence of that amendment. But the point of *Festo* is that some grounds for rejection, and hence reasons for amendment, support later prosecution history estoppel and some do not. The Federal Circuit has transitioned to a standard that ignores the *rationale* behind the amendment. Its claim in *Research Plastics* that "the purpose of the amendment was to avoid rejection based on rib placement" is just another way of saying that during prosecution the patent owner was forced to add a specification about rib placement—i.e., that the subject matter of the amendment related to the placement of ribs in the tube. A genuine inquiry into the purpose of the amendment would have asked why the patent owner had to add the rib specification. If the answer had been to avoid an enablement rejection (as here) then that purpose might have been only tangential to the accused equivalent. As it happened, the purpose of the amendment was to avoid rejection on the ground that without the new rib placement the claimed invention was obvious in light of prior art. Given that purpose, prosecution history estoppel would be appropriate whenever an alleged equivalent related to rib placement—and the Federal Circuit's oversimplification of the legal issue was effectively harmless error.

The Federal Circuit's legal error manifests itself where the rationale for the amendment does not support estoppel even though the *result* of the amendment bears a more than tangential relation to the equivalent in question. As discussed *supra*, the purpose of the amendment in this case

was distinct from the result of the amendment. The purpose of the amendment was to satisfy the enablement requirement. As one way of satisfying this rejection, the patentee chose to amend the claim by specifying thread depth. But this did not surrender every other equivalent way of satisfying the enablement rejection, any more than equivalents would have been surrendered had the thread depth language been included in the original claim, before amendment. The Federal Circuit's conflation of purpose with result, here and in *Research Plastics*, prevents it from recognizing that distinction.

As the petition pointed out, the Federal Circuit also employed an incorrect legal standard in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2270 (2007). There too, the Federal Circuit ignored the rationale underlying the amendment in question and instead relied solely on the amendment's subject matter, which was compared to the accused equivalent. The amendment in question was to overcome a prior art rejection, where the art taught a non-naturally occurring protein, but did not specify the length of the amino acid sequence. *See id.* at 1314-15. The patentee chose amino acid length as the basis for distinguishing the invention over this cited art, rather than choosing from a number of other grounds which also could have successfully served as a basis of distinction. The Federal Circuit penalized Amgen for that choice, even though the length of the amino acid sequence was only indirectly related to the rationale underlying the patent amendment.

Respondents point to *Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), and *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841 (Fed. Cir. 2006), as the lone post-*Festo* examples where the Federal Circuit concluded that the rationale underlying an amendment bore no more than a tangential relation to the equivalent in question. In both cases, the patentee successfully rebutted the presumption of prosecution history

estoppel. But these past decisions have been supplanted by more recent opinions such as this case and *Amgen*, which eviscerate the "tangential relation" test by focusing only on the subject matter of an amendment and ignoring its purpose. Indeed, in this case Judge Rader noted his belief that *Insituform* and *Primos* could easily have come out the other way—which is certainly true in light of the court's new understanding of the law. *See* Pet. App. 19a (Rader, J., concurring). If cases similar to *Insituform* and *Primos* arose tomorrow, the Federal Circuit's reasoning in this case and in *Amgen* would lead it to hold that the tangential relation test has not been satisfied.

4. Respondents accuse the petition's Question Presented of being too argumentative, but the substance of their objection is simply that they disagree with petitioner's portrayal of the scope and basis of the Federal Circuit's decision. This is a sideshow. The Question Presented and petition obviously made the substance of the dispute here clear to respondents. Their opposition brief squarely addresses whether the Federal Circuit materially altered this Court's established "tangential relation" test for rebutting the presumption of prosecution history estoppel—the issue posed in the Question Presented in the petition. The respondents also exercised the option to rephrase the Question Presented to identify what *they* perceive the issue to be, *see Almota Farmers Elevator & Warehouse Co. v. United States*, 409 U.S. 470, 473 & n.1 (1973), in a manner suggesting disagreement with petitioner's substantive argument but also recognition of the question raised. If this Court would prefer that briefing proceed under a different formulation of the question, it may of course adopt its own phrasing in the order granting certiorari.

5. Respondents incorrectly contend that the interlocutory posture of this case makes review inappropriate. The Federal Circuit's decision precludes infringement of the asserted claims of the '555 Patent based on Medtronic's redesigned screws, even though the case was remanded for

further factual findings on infringement theories against other Medtronic products. The interlocutory posture is no reason to defer review. An interlocutory posture is "no impediment to certiorari where the opinion of the court below has decided an important issue, otherwise worthy of review, and Supreme Court intervention may . . . hasten or finally resolve the litigation." Robert L. Stern et al., *Supreme Court Practice* § 4.18 (8th ed. 2002). The legal question presented in this petition turns on the proper interpretation of this Court's precedent. The balance between prosecution history estoppel and the doctrine of equivalents depends on this Court correcting the Federal Circuit's efforts to skew that balance.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted,

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